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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,490	10/03/2003	Derek Lydiate	11089.0003.NPUS01	8191

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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/678,490	LYDIATE ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 3, 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to a method of selecting for a plant that comprises a coding region of interest, classified in class 800, subclass 288, for example.

II. Claims 11-13, drawn to a method of selecting a transgenic plant that comprises a coding region of interest, classified in class 800, subclass 278, for example.

III. Claim 14, drawn to a method of selecting a transgenic plant that comprises a coding region of interest, classified in class 800, subclass 278, for example.

IV. Claims 15-19, drawn to a method of selecting a transgenic plant that comprises a coding region of interest, classified in class 800, subclass 278, for example.

V. Claims 20-21, drawn to a plant cell, tissue, seed or plant, classified in class 800, subclass 298, for example.

VI. Claim 22, drawn to a plant cell, tissue, seed or plant, classified in class 435, subclass 419, for example.

VII. Claim 23, drawn to a plant cell, tissue, seed or plant, classified in class 800, subclass 298, for example.

VIII. Claim 24, drawn to a plant cell, tissue, seed or plant, classified in class 435, subclass 419, for example.

IX. Claim 25, drawn to a construct, classified in class 435, subclass 320.1.

X. Claim 26, drawn to a construct, classified in class 435, subclass 320.1.

XI. Claim 27, drawn to a pair of constructs, classified in class 435, subclass 320.1.

XII. Claim 28, drawn to a pair of constructs, classified in class 435, subclass 320.1.

XIII. Claim 29, drawn to a method of selecting for a plant that comprises a coding region of interest, classified in class 800, subclass 278, for example.

For invention I above, restriction to a single first coding region (reporter protein, enzyme, antibody, indole acetamide hydrolase, methoxinine dehydrogenase, rhizobitoxine synthase or L-N-acetyl-phosphinothricin deacylase), a single repressor and operator sequence combination (Ros, Tet, Sin3 or Ume6), and a single pharmaceutically active protein (growth factors, growth regulators, antibodies, antigens, interleukins, insulin, G-CSF, GM-CSF, VG-CSF, M-CSF, interferons, blood clotting factors, transcriptional protein or nutraceutical protein) is also required under 35 USC 121. Therefore, if invention I is elected, a single first coding region and a single repressor and operator sequence combination and a single pharmaceutically active protein must also be elected.

The inventions are distinct, each from the other because of the following reasons:

The proteins encoded by the first coding region of invention I (reporter protein, enzyme, antibody, indole acetamide hydrolase, methoxinine dehydrogenase, rhizobitoxine synthase or L-N-acetyl-phosphinothricin deacylase) differ from each other in primary amino acid sequence and specific activities. The repressor and operator sequence combinations of invention I (Ros, Tet, Sin3 or Ume6) differ from each other in primary nucleotide sequence and specific activities. The pharmaceutically active proteins of invention I (growth factors, growth regulators, antibodies, antigens, interleukins, insulin, G-CSF, GM-CSF, VG-CSF, M-CSF, interferons, blood clotting

factors, transcriptional protein or nutraceutical protein) differ from each other in primary amino acid sequence and specific activities and pharmaceutical effects.

Invention I and inventions II-IV, VI, VIII-IX and XI-XIII are distinct inventions. The method of invention I does not require the use of or result in the production of the plant cell, tissue, seed and plant of inventions VI and VIII. The method of invention I does not require the use of or result in the production of the constructs of inventions IX and XI-XII. The method of invention I utilizes different materials and method steps than the methods of inventions II, IV and XIII. The method of invention I utilizes different method steps than the method of invention III.

Inventions VII and X and invention I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the plant of invention VII can be used in a materially different process of using that product, such as a breeding method. In the instant case the construct of invention X can be used in a materially different process of using that product, such as a hybridization method.

Invention I and invention V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the

instant case the plant cell, tissue, seed and plant of invention V can be made by another and materially different process, such as by cotransformation.

Invention II and inventions III-IV, VI, VIII and XI-XIII are distinct inventions. The method of invention II does not require the use of or result in the production of the plant cell, tissue, seed and plant of invention VI. The method of invention II does not require the use of or result in the production of the constructs of invention XI. The method of invention II utilizes different materials and method steps than the methods of inventions III-IV. The method of invention II utilizes different method steps than the method of invention XIII.

Inventions IX-X and invention II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the constructs of inventions IX-X can be used in a materially different process of using that product, such as a hybridization method.

Invention II and inventions V and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the plant cell, tissue, seed and plant of inventions V and VII can be made by another and materially different process, such as by cotransformation.

Invention III and inventions IV, VI-IX and XI-XIII are distinct inventions. The method of invention III does not require the use of or result in the production of the plant cell, tissue, seed

and plant of inventions IV and VI-VIII. The method of invention III does not require the use of or result in the production of the constructs of inventions IX and XI-XII. The method of invention III utilizes different materials and method steps than the methods of inventions IV and XIII.

Inventions VII and X and invention III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the plant of invention VII can be used in a materially different process of using that product, such as a breeding method. In the instant case the construct of invention X can be used in a materially different process of using that product, such as a hybridization method.

Inventions III and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the plant cell, tissue, seed and plant of invention V can be made by another and materially different process, such as by cotransformation.

Invention IV and inventions V, VIII, X-XI and XIII are distinct inventions. The method of invention IV does not require the use of or result in the production of the plant cell, tissue, seed and plant of inventions VI-VII. The method of invention IV does not require the use of or result in the production of the constructs of inventions X-XI. The method of invention IV utilizes

different materials and method steps and produces a different product than the method of invention XIII.

Inventions VII, IX and XI and invention IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the plant of invention VII can be used in a materially different process of using that product, such as a breeding method. In the instant case the constructs of inventions IX and XI can be used in a materially different process of using that product, such as a hybridization method.

Inventions IV and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the plant cell, tissue, seed and plant of invention VI can be made by another and materially different process, such as by cotransformation.

Invention V and inventions VI-XII are distinct inventions. The plant cell, tissue, seed and plant of invention V comprises a third nucleotide sequence not comprised by the plant cell, tissue, seed and plant of inventions VI and VII. The plant cell, tissue, seed and plant of invention V comprises a second nucleotide sequence not comprised by the plant cell, tissue, seed and plant of invention VII. The plant cell, tissue, seed and plant of invention V comprises a first nucleotide sequence not comprised by the plant cell, tissue, seed and plant of invention VIII. The plant cell,

tissue, seed and plant of invention V differs in structure, function, composition and classification from the DNA constructs of inventions IX-XII.

Inventions XIII and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the plant cell, tissue, seed and plant of invention VII can be made by another and materially different process, such as by cotransformation.

The plant cell, tissue, seed and plant of invention VI comprises a second nucleotide sequence not comprised by the plant cell, tissue, seed and plant of invention VII. The plant cell, tissue, seed and plant of invention VI comprises a first nucleotide sequence not comprised by the plant cell, tissue, seed and plant of invention VIII. The plant cell, tissue, seed and plant of invention VI differs in structure, function, composition and classification from the DNA constructs of inventions IX-XII. The plant cell, tissue, seed and plant of invention VI are not required to practice or produced by the method of invention XIII.

Invention VII and inventions VIII-XII are distinct inventions. The plant cell, tissue, seed and plant of invention VII comprises a first nucleotide sequence not comprised by the plant cell, tissue, seed and plant of invention VIII. The plant cell, tissue, seed and plant of invention VII differs in structure, function, composition and classification from the DNA constructs of inventions IX-XII.

Inventions XIII and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as

claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the plant cell, tissue, seed and plant of invention VII can be made by another and materially different process, such as by cotransformation.

Invention VIII and inventions IX-XIII are distinct inventions. The plant cell, tissue, seed and plant of invention VIII differs in structure, function, composition and classification from the DNA constructs of inventions IX-XII. The plant cell, tissue, seed and plant of invention VIII are not required to practice or produced by the method of invention XIII.

Invention IX and inventions X-XII are distinct inventions. The construct of invention IX does not comprise the second nucleotide sequence comprised by the constructs of inventions X-XII, or the third nucleotide sequence comprised by the constructs of inventions X and XII.

Inventions IX and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the construct can be used in a materially different process of using that product, such as a hybridization method.

Invention X and inventions XI-XII are distinct inventions. The construct of invention X does not comprise the first nucleotide sequence comprised by the constructs of inventions XI-XII.

Inventions X and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the construct can be used in a materially different process of using that product, such as a hybridization method.

Invention XI and inventions XII-XIII are distinct inventions. The constructs of invention XI comprise a third coding region that is not comprised by the constructs of invention XII. The constructs of invention XI are not required to practice or produced by the method of invention XIII.

Inventions XII and XIII are distinct inventions. The constructs of invention XII are not required to practice or produced by the method of invention XIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, their recognized divergent subject matter, and the requirement for different areas of search, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Primary Examiner
Art Unit 1638

CC

Cynthia Collins
2/21/06